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REMARKS

The requested amendments are intended to clearly distinguish the current invention from US 6,319,712 (Meenen et al 2001). The '712 patent was not previously known to the Applicant or the undersigned attorney, and the Examiner is sincerely thanked for locating it, so that the issues it raises can be resolved.

Meenen et al '712 is expressly limited to "biohybrid" materials, which use a porous matrix to culture and protect living transplanted cells, while the cells regenerate new cartilage. As determined by Meenen et al, if certain molecules that help make synovial fluid slippery are allowed to permeate into the area where transplanted cells are regenerating new cartilage, then the newly-formed cartilage cannot form or function properly. Accordingly, Meenen developed a semi-permeable membrane that would enable water to permeate through the membrane, while keeping out molecules that would interfere with regeneration of new cartilage.

That is an interesting concept, and it may work, some day. However, any such efforts to regenerate new cartilage, using transplanted cells protected by porous materials that will be dissolved and resorbed, must somehow overcome a crucial and unavoidable problem.

At some point, during any process of resorption, as strands or membranes of a cell-culturing matrix are gradually dissolved while being subjected to the types of forces that are imposed on loaded and stressed joints (such as knees or hips, the joints that most often require repair), partially-dissolved strands, flakes, or other segments of the resorbable material (which necessarily includes the resorbable surface membrane) will be dislodged, and separated, from the semi-dissolved implanted matrix material. When that happens, in a loaded and stressed joint, the partially-dissolved segments become unwanted debris, which pose huge risks of abrading and damaging the crucial and extremely vulnerable surfaces of the new cartilage being formed by the transplanted cells.

That problem cannot be avoided, or eliminated, by any solid material that is designed to replace cartilage in a loaded joint, and that will be gradually dissolved and resorbed, after implantation. In other settings, such as in regenerating an internal organ, that factor might not make a difference. But when it occurs in a loaded and stressed joint, such as a knee or hip, it will pose a huge problem, which absolutely demands attention. And yet, Meenen '712 offers no suggestions, of any sort, about how that problem might be solved.

For those and other reasons, the Applicant herein took a completely different route, and began designing cartilage-replacing implants that are designed to be permanent, and that will not dissolve, resorb, or release debris, but that also are thin and flexible, so that they can be implanted arthroscopically. That approach required numerous other problems to be solved (such as, for example, how to adequately reinforce a soft gel that must last for decades, how to affix a soft gel to a hard anchoring device, and how to design such an implant that can be affixed to a hard bone surface, using nothing but arthroscopic access). Through persistence and diligence, those problems have indeed been solved, by the Applicant.

Accordingly, the claims in this application are limited by the amendments above, to make it clear that they cover only non-resorbable implants. This removes them completely from the teachings of Meenen '712.

Furthermore, because a completely new set of complex and difficult problems arise if an inventor stops trying to use transplanted cells to regenerate cartilage, and instead tries to develop a non-resorbable and permanent synthetic implant to replace rather than regenerate cartilage, no presumption of obviousness arises from the Meenen '712 teachings.

On that subject, it is pointed out that, because Meenen '712 did indeed teach a semi-permeable membrane, all claims have been amended, so that they cover devices that are more than just a membrane. In particular, claims 24-27, as amended, cover non-resorbable implant devices which include a semi-permeable

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membrane as one component, and claims 34-36 cover synthetic and nonresorbable hydrogel material that is designed and suited for replacing mammalian cartilage, and that includes a semi-permeable membrane as one component.

CONCLUSION

For the reasons stated above, it is believed that if these amendments and remarks are entered into the record, then the amended claims will be in condition for allowance. If any questions arise, please contact the undersigned at 314-822-8558.

Respectfully submitted,

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